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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,205	03/24/2004	Suzanne T. Ildstad	17541-040001	3925

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EXAMINER	
SKELDING, ZACHARY S	
ART UNIT	PAPER NUMBER
1644	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/808,205	IIDSTAD, SUZANNE T.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Zachary Skelding, Group Art Unit 1644.

2. Applicant's election, without traverse, of October 20, 2006 is acknowledged.

3. Claims 1-30 are pending.

4. In response to the Restriction Requirement of August 28, 2006, Applicant elected Group I, without traverse.

   Hence, claims 1, 2 and 7-27 are under consideration as they read on a method for bone marrow transplantation comprising administering to recipient antibodies that specifically deplete αβ- and γδ-TCR, followed by delayed transplantation with donor hematopoietic stem cells matched at the MHC I K locus with the recipient hematopoietic microenvironment.

   Claims 3-6 and 28-30 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being directed to a non-elected invention.

5. It is noted that there are two #25 claims, therefore, for the purposes of the instant Office Action, these claims will be referred to as 25A and 25B. Appropriate correction is required. Moreover, applicant is reminded that adding a claim would appear to increase the number of originally filed claims and therefore additional fees may be due.

6. It is further noted that the preamble of independent claims 1 and 25B recite "a method for conditioning a recipient for bone marrow transplantation comprising..." however the steps that follow recite not only applying conditioning agents to the recipient but also "administering hematopoietic stem cells from a donor." Thus, claims 1 and 25B are directed to both conditioning a recipient ***AND*** transplanting donor cells into the recipient.

   In contrast, the preamble of independent claim 16, which recites nearly the same steps as claims 1 and 25B, recites "a method for partially or completely reconstituting a mammal's lymphohematopoietic system". The preamble of claim 16 is more descriptive of the outcome of the actual steps involved in the methods of claims 1 and 25B.

   Accordingly, for the purposes of examination, claims 1 and 25B will be restricted as if their preambles recited "a method for partially or completely reconstituting a mammal's lymphohematopoietic system", like the preamble of claim 16.

   Applicant is invited to clarify for the record what is being claimed in claims 1 and 25B and if they somehow differ from claim 16.

7. It is further noted that applicant neglected to elect a species of disease/condition that the recipient is suffering from as required in the Restriction Requirement of August 28, 2006. Thus, applicant's election is considered a non-responsive, albeit bona fide attempt to reply.

Nevertheless, in the interest of compact prosecution the following new Restriction Requirement is being issued rather than a notice of non-responsive amendment.

8. Upon further consideration, the previous restriction requirement is hereby ***VACTATED***. A new Restriction Requirement is set forth below.

The Examiner apologizes for any inconvenience to applicant in this matter.

Restriction Requirement

9. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antibodies*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells, classified in Class 424, subclass 130.1.

II. Claims 1, 2, 7-25A and 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antibodies*** that specifically deplete ***CD8***$^+$ T-cells, classified in Class 424, subclass 130.1.

III. Claims 1, 2 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antibodies*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 424, subclass 130.1.

IV. Claims 1, 3-5 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antisense DNA*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells, classified in Class 514, subclass 44.

V. Claims 1, 3-5, 7-25A and 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antisense DNA*** that specifically deplete ***CD8***$^+$ T-cells, classified in Class 514, subclass 44.

VI. Claims 1, 3-5 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antisense DNA*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 514, subclass 44.

VII. Claims 1, 6 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***cytotoxic drug*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells, classified in Class 514, subclass 1.

VIII. Claims 1, 6, 7-25A and 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***cytotoxic drug*** that specifically deplete ***CD8***$^+$ T-cells, classified in Class 514, subclass 1.

IX. Claims 1, 6 and 7-25A, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***cytotoxic drug*** that specifically deplete ***αβ- and γδ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 514, subclass 1.

X. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antibodies*** that specifically deplete ***αβ-TCR***$^+$ T-cells, classified in Class 424, subclass 130.1.

XI. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antibodies*** that specifically deplete ***αβ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 424, subclass 130.1.

XII. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antisense DNA*** that specifically deplete ***αβ-TCR***$^+$ T-cells, classified in Class 514, subclass 44.

XIII. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***antisense DNA*** that specifically deplete ***αβ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 514, subclass 44.

XIV. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***cytotoxic drug*** that specifically deplete ***αβ-TCR***$^+$ T-cells, classified in Class 514, subclass 1.

XV. Claims 25B-27, drawn to a method for partially or completely reconstituting a mammal's lymphohematopoietic system comprising administering ***cytotoxic drug*** that specifically deplete ***αβ-TCR***$^+$ T-cells **AND** ***CD8***$^+$ T-cells, classified in Class 514, subclass 1.

XVI. Claims 28-30, drawn to a method for conditioning a recipient for bone marrow transplantation comprising subjecting said subject to total body irradiation followed by infusion with donor stem cells, classified in Class 424, subclass 93.7.

10. Inventions I-XVI are directed to related methods. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed have materially different design, mode of operation, function, or effect.

    More particularly, the claims employ different T cell depleting agents such as "antibodies", "antisense DNAs", "cytotoxic drugs" and "radiation" which are patentably distinct because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility.

    Furthermore, each particular T cell depleting agents is patentably distinct one from the other because they recognize and deplete distinct subsets of T-cells, and therefore each T cell depleting agent in turn must have a specific structure which enables it, for example, to distinguish a $CD8^+$ T-cell from a ***αβ- and γδ-TCR***$^+$ T-cells, **OR** for example, to distinguish, ***αβ- and γδ-TCR***$^+$ T-cells from ***αβ-TCR***$^+$ T-cells.

    Moreover, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

    Furthermore, the inventions as claimed require non-coextensive searches in the scientific literature.

    Therefore, each product is patentably distinct, and searching of these inventions together would impose an undue burden.

11. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

Species Election

12. This application contain claims directed to the following patentably distinct species of the claimed invention:

    If applicant elects any one of **Groups I-XVI,** for the claimed "method for partially or completely reconstituting a mammal's lymphohematopoietic system" applicant is required to elect a ***"specific use for the method in the treatment of"***, as recited in the instant specification at page 14, paragraph [00052] and in claims 18-21 for example, **"AIDS" *OR* "diabetes" *OR* "thalassemias" *OR* "sickle cell disease" *OR* "solid organ transplantation" *OR* "multiple sclerosis".**

    These ***"specific use for the method in the treatment of"*** are patentably distinct because they differ in etiologies and therapeutic endpoints. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these species together.

    Applicant is required under 35 USC 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held allowable.

13. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

    Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

    Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
January 7, 2007

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TC 1600
1/8/07